

### REMARKS

Claims 1, 3, 7, 17, 19, and 22, as amended, are pending in the instant application. Claims 2, 5, 6, 18, 20, and 21 have been cancelled without prejudice or disclaimer. Support for the amendments to the claims can be found in the specification at, for example, pages 4-6, 8-12, and 14. No new matter has been added as a result of the above-described amendments.

#### **1. Claim 1**

Applicants have amended claim 1 to recite a reagent for detecting human papilloma virus (HPV) DNA in a cell sample which indicates the patient providing the cell sample is at risk for cancer comprising a plurality of genomic HPV DNA probe sets, wherein each probe set comprises a plurality of nucleic acid molecules that detectably hybridize to substantially all of the full-length genomic sequence of HPV types 16, 18, 31, 33, 35, or 51.

Applicants contend that support for the amendments to claim 1 can be found in the specification and knowledge in the art at the time the instant application was filed. For example, the specification teaches that the reagent of the instant invention comprises a plurality of genomic probes to certain HPV types (page 4). The specification also teaches a reagent for detecting HPV DNA comprising probes derived from the genomic sequences of HPV types 16, 18, 31, 33, 35, or 51 (pages 6 and 8). In particular, the specification teaches a reagent for detecting HPV DNA that is prepared by individually labeling (by nick translation) six separate plasmids, each of which contains the genomic sequence of either HPV type 16, 18, 31, 33, 35, or 51, and then mixing the labeled nucleic acid molecules generated in these individual labeling reactions to form a single reagent (page 8). The specification also teaches that the cloned HPV genomes used to generate the labeled nucleic acid molecules may constitute less than the full-length genomic sequence of a particular HPV type (page 5), and further, that other types of labeling techniques (*e.g.*, PCR and random priming) may be used to generate the labeled nucleic acid molecules (page 5). Applicants contend that one of ordinary skill in the art would readily understand that a reagent prepared using the procedures explicitly taught in Example 1 (*i.e.*, mixing the labeled nucleic acid molecules generated by nick translation of six separate plasmids comprising the genomic sequence of either HPV type 16, 18, 31, 33, 35, or 51) would comprise a plurality of labeled nucleic acid molecules that detectably hybridize

to substantially all of the full-length genomic sequence of HPV types 16, 18, 31, 33, 35, or 51. Applicants also contend that one of ordinary skill in the art would readily understand that the reagent of the instant invention could also be prepared, for example, in amplification (*i.e.*, PCR) or random priming reactions.

## 2. Claim 3

Applicants have amended claim 3 to recite the reagent of claim 1, wherein the genomic HPV DNA probes also hybridize to substantially all of the full-length genomic sequence of HPV types 39, 45, 52, 56, 58, 59, 68 and 70.

Applicants contend that support for the amendments to claim 3 can be found in the specification and knowledge in the art at the time the instant application was filed. For example, the specification teaches that by exploiting the cross-reactivity of the disclosed genomic HPV DNA probes, the reagent of the instant invention can be used to detect HPV types other than those HPV types that are completely complementary to the probes of the reagent (page 4). The specification also teaches a reagent for detecting HPV DNA comprising probes derived from six HPV types which cross-react with a total of thirteen HPV types (page 4). In particular, the specification teaches that a reagent comprising probes derived from the genomic sequences of HPV types 16, 18, 31, 33, 35, or 51 also hybridizes to (*i.e.*, cross-reacts with) the genomic sequences of HPV types 39, 45, 52, 56, 58, 59, 68 and 70 (pages 8, 9, and 14).

## CONCLUSIONS

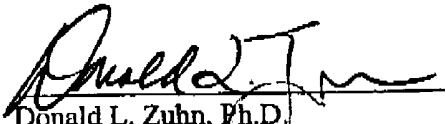
Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner Switzer believes it to be helpful, she is invited to contact the undersigned representative by telephone at 312-913-0001.

Respectfully submitted,  
**McDonnell Boenken Hulbert & Berghoff**

Dated: August 4, 2004

By:

  
Donald L. Zuhn, Ph.D.  
Reg. No. 48,710